SCOR
Southeast Clinical Oncology Research Consortium

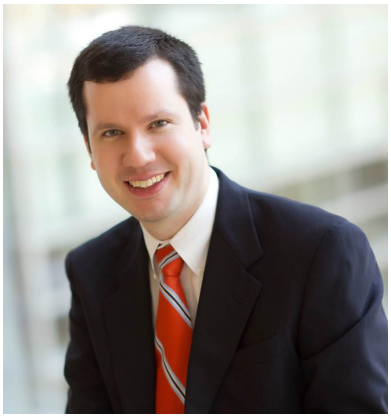
CONSORTIUM CONNECTIONS

Fall 2015

PI/Co-PI Corner

(Drs. Atkins, Bearden, Hopkins, and Griffin)

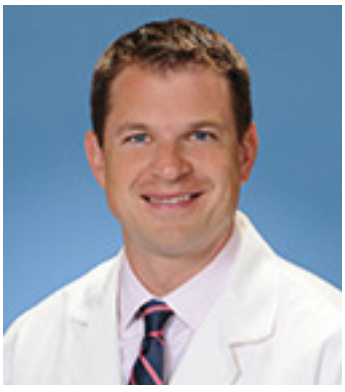
We have determined the time has come to take the next step in preparing for our future leadership by choosing Young Investigators (YIs) to assume greater responsibility in the leadership of SCOR. There have been five YIs who have played an integral role in learning the administrative function of SCOR. The five YIs are: Drs. Amy Curtis, Steve Duffy, Kathleen Elliott, Billy Irvin, and Jeremy Kilburn. Four of them are now at a point in their career where they are able to actively participate in the leadership of SCOR. The current leadership is proud to announce the selection of Dr. Amy Curtis (Spartanburg) and Dr. Billy Irvin (Richmond) to assume the roles of PI with Dr. Steve Duffy (Richmond) and Dr. Jeremy Kilburn (Spartanburg) to assume the roles of Co-PI. The date for the official transition from the current to the new leadership is to be determined. We will provide mentoring in preparation of future leadership and direction in the next NCORP Grant submission in 2018. We will become "Emeritus PIs and Co-PIs" and will continue to support and provide direction for the new leadership to ensure a smooth transition and stable environment as warranted by the scope of the award.



Dr. Billy Irvin

Dr. Amy Curtis

Dr. Steve Duffy



Dr. Jeremy Kilburn

Inside this Issue

SCOR Administrative Office Staff

Susan Tuttle, RN CCRP
Administrator
336-448-1422

Robin Burgess, RN, CCRP
Program Manager
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Robyn DiRusso, RN, BSN
Program Coordinator
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Debbie Eaton
Business Coordinator
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Belenda Slate, BAS
Protocol Systems Specialist
336-448-1418

Kim Fulton
Administrative Assistant
336-448-1417

Vision of New PIs

(Dr. Amy Curtis and Dr. Billy Irvin)
Over the next five years, the strategy for the SCOR NCORP should be to continue identifying and investing in physicians who are willing and capable of enrolling patients on NCI clinical trials. By continuing to foster the investigators we have, as well as recruit new invested physicians, we hope to continue to grow our accrual numbers and provide world class care to patients. With SCOR being the largest NCORP, the aim over the next 5-10 years is to be at the top of accruals, conduct high quality research, and have efficient operations.

Top Accruals
In order to have continued growth, we need to not just foster the current relationships, but to expand our relationships to new physicians and staff. This strategy may not require the addition of new sites but the current members may expand and recruit new members. In order to accomplish these goals, the SCOR membership needs to improve collaboration and sharing of best practices through SCOR meetings and individual sessions either formally or informally. SCOR meetings can provide an atmosphere to facilitate accruals and shared experiences. Increased participation through attendance to research base meetings by a greater number of SCOR investigators will help to invigorate investigators and promote more "voices from the trenches." This will ensure inclusion of community sites for all studies,including foundation studies.

Young Investigator Involvement
A clear and necessary focus of SCOR has been and should continue to be to grow and mentor young investigators to assume a position of leadership within the next five years. Over the next five years, the mentor/mentee relationship will be key to ensure a strong transition in leadership.

High Quality Research
Research nurses and research associates at the community level have a tremendous responsibility and need to serve as a major resource in achieving high quality audits and data reviews. The need to disseminate the excellent clinical trial training done by Alliance, NRG, and SWOG is a top priority. We would like to focus on local community site research staff, as strong staff at the community level will take some pressure off the Administrative Office.

The need to continue to provide the opportunity through audits to fine tune the quality of SCOR research is imperative.

Efficient Operations
The SCOR Administrative Office does a tremendous amount of work to support the research done at the community level. Another focus is to prepare for an eventual transition of administrative staff, as the administrative staff is the true lifeblood of the organization. The membership benefits from the collective experience of the leadership and team of individuals in the Administrative Office. This office is the core of SCOR and the vision going forward.

Cancer Care Delivery Research (CCDR)
Within 5-10 years, we will have an opportunity to focus and introduce CCDR to SCOR communities. We will need to bring this forth in a positive and opportunistic way to allow it to grow, hopefully, with a clear vision from the NCI at that time.

We look forward to a year of opportunities engaging in community activities and getting to know each of you.

New SCOR Members

New SCOR Physician Members

Anderson, SC
William S. Buice, MD
Louay Hanna, MD

Asheville, NC
Michelle LeBlanc, MD
Lynn Howie, MD
Rachel Raab, MD

Charleston, SC
Ashley Sumrall, MD

Charlotte, NC
Jennifer Dallas, MD
Catherine Moore, MD
Jason Shultz, MD

Florence, SC
Karim Tazi, MD

Gastonia, NC
Jerome M. Butler, MD
Robert M. Doline, MD

Goldsboro, NC
Debra Miller, MD

Greensboro, NC
Vinay K. Gudena, MD
James A. Palermo, MD
Shannon Penland, MD
Yan Feng, MD

Hendersonville-Park Ridge, NC
Deborah Bradley, MD
Gregg H. Goldin, MD

Richmond, VA
Timothy Wallace, MD

Savannah, GA
William E. Burak, MD

Spartanburg, SC
Caio Rocha-Lima, MD
Melanie Thomas, MD

Winston Salem, NC
Joshua Trinidad, MD

New SCOR Research Staff

Asheville, NC
Sarah Kuhl, RN
Catherine McPolin, RN, BSN, OCN, CCRP

Cary, NC
Allison Pereklita, PA-C
Clarissa A. Urban, PA

Charleston, SC
Jennifer Corson, RN, ADN

Charlotte, NC
Heather G. Causey
Simone Tomlinson, BS
Jerrilynn H. Wright, BS

Florence, SC
Lisa McDonald, RN

Goldsboro, NC
Alyssa Hill, BS
Denise D. Weir

Greensboro, NC
Gina Dixon, RN, BSN, MHA, OCN
Barbara Puhala
Carolyn D. Thomas, RN

Greenville, SC
Amanda Lowery, BSN
Veronica Trevino, LPN

Hendersonville-Park Ridge, NC
Ray Diaz
Tia Robinson

Kingsport, TN
Justin Reynolds, BS

Pinehurst, NC
Shauna Eggertson, RN, BSN

Richmond, VA
Wendy I. Jenvey, CCRC, BSN
Deborah Myers, RN, OCN
Mary "Katie" Williams, RN

Spartanburg, SC
Andrea G. Adams
Laura Bailey, BS
Lisa Kirby
Kenneth Kuenzli, RN
Luann Lester, RN
Kamara L. Mertz-Rivera, MA
Heather D. Weathers, RN

Winston Salem, NC
Meredith Bullard, BS, MS, AA
Dana Curlings
April Sanspree, RN

New SCOR Community Responsible Investigator (CRI)

Steven A. Akman, MD
Charleston, SC

New SCOR Study Coordinator

Sarah Kivett, RN
Statesville, NC

SCOR NCORP Accural Reports-Year 1

Total NCI Accrual	Credit	NCI Credit Quota	Deficit	NCI %
942	362.85	615	252.15	59

SCOR Accrual Performance for Year 01 (8/1/14 – 7/31/15)

MD	Accruals	MD	Accruals	MD	Accruals	MD	Accruals
Lungreen	53	Mohamed	17	Harkness	11	Kuehn	7
Monitto	35	Sundborg	17	Kilburn	11	McDonald	7
Katragadda	30	King	16	Lassiter	11	Anthony	7
Kuzma	28	Willard	16	Fried	10	Pederson	7
Choksi	27	Graham	15	Magrinat	10	Radford	7
Kasbari	26	Nelson	15	Curtis	9	Chrysson	7
Corso	23	Acker	14	Doster	9	Hopkins	7
Dyar	23	Pohlmeyer	14	Gorsuch	9	Lewis	6
Bowers	20	Sherrill	14	Misra	9	Mehta	6
Chay	20	Vidito	14	Williams-Wuch	9	Miller	6
Atkins	19	Chang	13	Yang	9	Pandit	6
Pollack	19	Finnegan	13	Shearer	8	Warlick	6
Byron	17	Moore	13	Ellison	7		
Curran	17	Patel	13	Griffin	7		
89 MDs: 1-5 Accruals		95 MDs: 0 accruals					

SCOR Accrual by Community for Year 01 (8/1/14 – 7/31/15)

Community	NCI Accruals		Total	Industry	Overall Total
	RX	CC			
Anderson	12	12	24	0	24
Asheville	54	25	79	8	87
Cary	15	0	15	0	15
Charleston	21	3	24	4	28
Charlotte	43	13	56	16	72
Danville	4	1	5	0	5
Florence	6	0	6	0	6
Gastonia	5	59	64	0	64
Goldsboro	53	15	68	2	70
Greensboro	71	27	98	24	122
Greenville	48	5	53	0	53
Hendersonville/Pardee	10	11	21	0	21
Hendersonville/Park Ridge	0	0	0	0	0
High Point	1	1	2	0	2
Kingsport	8	0	8	0	8
Martinsville	8	23	31	0	31
Pinehurst	15	132	147	1	148
Richmond	12	6	18	0	18
Savannah	10	4	14	3	17
Spartanburg	150	22	172	0	172
Statesville	3	1	4	0	4
Winston Salem	18	15	33	27	60
TOTAL	**567**	**375**	**942**	**85**	**1027**

SCOR NCORP 1st Quarter Accural Reports-Year 2

SCOR 1st Quarter Accruals by Community for Year 02 (8/1/15 – 10/31/15)				
Community	NCI Accruals		Credits	Foundation
	RX	CC		
Anderson	3	2	3.0125	
Asheville	20	3	6.988	4
Cary	0	0	0	
Charleston	2	3	1.0375	6
Charlotte	18	3	7.2125	11
Danville	0	0	0	
Florence	0	0	0	
Gastonia	2	22	6.1325	
Goldsboro	17	0	7.1385	
Greensboro	12	5	7.8375	5
Greenville	29	4	6.8375	
Hendersonville/Pardee	1	2	2.0375	
Hendersonville/Park Ridge	0	0	0	
High Point	0	0	0	
Kingsport	1	0	0.125	
Martinsville	0	2	0.32	
Pinehurst	8	24	8.6475	3
Richmond	5	0	2.0125	
Savannah	4	0	1.375	
Spartanburg	29	8	13.7	
Statesville	0	0	0	
Winston Salem	1	0	.0625	
TOTAL	**152**	**75**	**74.4765**	**29**

SCOR Research Base Updates

NRG studies presented at ASTRO

The ASTRO annual meeting took place in San Antonio, Texas October 18-21, 2015. Twenty-two NRG studies were presented, including two at plenary sessions. SCOR is one of the top institutions accruing to NRG trials and our efforts along with other NRG members contributed to these important research findings.

Link for top accruing NRG sites
https://www.nrgoncology.org/About-Us/Membership/Outstanding-Site-Participation-Recognition

Link for all NRG abstracts presented at ASTRO 2015 https://www.nrgoncology.org/Portals/0/About%20Us/Meeting%20Schedules/NRG%202015%20ASTRO%20Presentations%20by%20Date.pdf

Great News from the ABR!

The American Board of Radiology (ARB) recently expanded the number of approved participation activities for Maintenance of Certification for radiation oncologists and medical physicists. Active participation in an NCI research base clinical trial meets the requirements of Part 4. For diagnostic radiologists, radiation oncologists, and interventional radiologists, entry of five or more patients in one year meets the requirement. For medical physicists, active participation in the credentialing activities will count.

For more information http://theabr.org/moc-ro-comp4#PQI FAQs

MATCH

"Excitement, Frustration, Hope, and Fear"

This has been a roller coaster ride and it's only been open a few months. As of November 5, 2015, more than 500 patients have been enrolled in the MATCH study (more than 50 from SCOR sites!). ***The study is now closed for interim analysis.*** The NCI and study leaders are hearing frustrations from investigators ***loud*** and ***clear***. The central lab is hiring additional staff to accommodate the overwhelming interest and number of samples. They anticipated receiving 20 samples a week and were receiving 20 a day! As of the above date, there is only the one patient receiving drug so, if you have a patient without an actionable mutation or are still waiting for results – you are ***not*** alone!

Amy Curtis, MD

SCOR Ranking within NCORP Community Sites

As the largest traditional Community Site NCORP, research bases have been reaching out to SCOR NCORP for participation in committees, panels, providing education, and podium presentations. SCOR is seen as a leader since there is a diversity of community sites, population, and providers. Kaiser Permanente NCORP is the only NCORP larger than SCOR but its model is quite different. Kaiser's model involves covering the patients whom they are providing insurance coverage plus Kaiser owns all institutions. SCOR's model is different and involves a clinical service area which provides clinical care to communities plus SCOR does not own any of the institutions. Kaiser does not treat medically underserved or uninsured patients but SCOR services significant disparities and the uninsured. SCOR members can all be proud of this strong consortium which is improving lives by bringing clinical trial participation with advanced therapies to the communities served.

SCOR Audit Updates

Preventative Measures based on Audit Findings

Regulatory:

- Revisions/Amendments/Updates have to be approved within 90 days of distribution by the research bases
- Continuing reviews should be accomplished within 365 days – some years may have 2 continuing reviews
- NCI CIRB original approvals, continuing reviews, and revision/amendment/update/ approvals should be printed off and kept in a regulatory binder or the documents saved on a flash drive to be referenced at audit time
- For SWOG, you will need to provide all consent forms changes associated with any revision/ amendment to the audit team.

Pharmacy:

- All shipping invoices/receipts should be kept with the DARFs to verify that the shipment date on the DARF corresponds to the date noted on the shipping invoice by the pharmacist receiving the drug.
- Unopened vials/bottles of drug should be returned to NCI/PMB/distributor or partial/ opened drug should be destroyed within 90 days of protocol closure, last patient treated, death or progression on study drug.

Patient Case Review:

1. **Consent:**
   - The most recent IRB approved consent forms should be utilized on all patients. Make sure you have a procedure to verify the most current consent form is used.
   - New risk information included in consent forms should be communicated as instructed in the cover memo for the revision to protocol patients at the next scheduled contact. Please read the cover memos closely to determine if patients are to be re-consented or just notified. Keep a list of all patients on the study in order to be able to reference the list when having to contact patients for new risk information.

2. **Eligibility:**
   - All pre-study laboratory tests are to be done as required. If any are not done for insurance or other reasons, please contact the study chair to verify if patient would still be eligible and note the reason in the source documentation.
   - Verify that the window from surgery/biopsy to registration is within the time requirement stated in the protocol eligibility section.
   - Any scans required prior to entry must be done prior to entry and not after registration, especially if confirming disease status.
   - If pain or fatigue scales are used to determine eligibility, make sure the patient understands clearly what you are wanting and if they are truly eligible based on their symptoms.
   - SWOG has a Registration Worksheet for each protocol located with the Master Forms Set. The bottom of the worksheet requires the investigator's signature affirming the eligibility for this patient has been met and the date affirmed. They will also accept the eligibility checklist signed and dated with the investigator's signature if you do not have the Registration Worksheet completed. Ideally you should complete the Registration Worksheet and have in hand when you register the patient through OPEN. A memo was distributed January 1, 2013 stating the registering investigator is required to sign this statement on the Registration Worksheet confirming the eligibility criteria has been met.

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Preventative Measures based on Audit Findings cont.

3. Treatment:

- Doses of study drug are to be calculated based on the mg/m2 or mg/kg as noted in the protocol. Verify that you are not overdosing or under-dosing the patient. Doses greater than or less than 10% of the correctly calculated dose is a Major deficiency.
- Doses of study drug are to be modified as noted in the protocol. Physicians cannot make modifications in doses that are not based on guidelines within the Dose Modification section of the protocol.
- Need to have a procedure in place to capture Performance Status at each required visit noted in the Study Parameters section of the protocol.

4. Disease Assessment/Outcome:

- Scans/tests/immunologic labs that determine the patient's response MUST be done at the designated time frames stated in the Study Parameters section of the protocol.

5. Toxicities:

- All toxicities experienced by the patient MUST be reported on the toxicity/adverse events data form with source documentation to verify. Attribution must also be stated with the listed toxicities. The Adverse Event Flow Sheet already sent to you by email can be utilized as source documentation to determine grade and attribution of toxicities. Failure to report multiple toxicities results in Major deficiencies at audit time.
- You MUST report serious adverse events (SAEs) as noted in the protocol section as soon as you are made aware of the SAE(s). Failure to report results in Major deficiencies at audit time.
- If toxicities are not reported within a timely manner (90 days), a Major deficiency will be assigned at audit time.
- When follow-up labs are not obtained following treatment, the toxicities cannot be assessed completely; therefore, a Major deficiency will be assigned at audit time.

6. Data Quality/Submission:

- Any Quality of Life (QoL) form required during the study MUST be submitted/entered into RAVE with source documents (original QoL forms) maintained for comparison at audit time.
- Tissue/blood/other specimens required at protocol entry or at designated intervals MUST be submitted as required per protocol. If not submitted, a Major deficiency will be assigned at audit time.
- Data during treatment and follow-up that is submitted greater than 3 months but less than 6 months after due date is considered a Lesser deficiency but data that is submitted greater than 6 months after due date is considered a Major deficiency. Baseline required data (pathology reports, forms, tumor assessments, etc.) due within 7-14 days after registration should be submitted during that time period. If you wait and submit the required data greater than 30 days but less than 90 days, this will be considered a Lesser deficiency. If you wait to submit the required data greater than 90 days, this will be considered a Major deficiency.
- Protocols requiring Interim toxicity evaluations must have clear documentation patient was assessed. (Ex.: S1014 and S0931)
- If patient is found to be ineligible for any reason, follow-up is to be continued as if the patient was still on study.

SCOR CCDR & CIRB Updates

SCOR CCDR Update: First CCDR Studies to Open

It has been a slow process to work through the approval process by the research bases and NCI for the proposed CCDR studies. SWOG has just received NCI approval for two adult CCDR studies. Both studies will be opened at the SCOR CCDR sites in the near future once distributed by SWOG. The two studies are:

1. SWOG S1417CD: "Implementation of a Prospective Financial Impact Assessment Tool in Patients with Metastatic Colorectal Cancer" (374 participants) was approved by NCI February 2, 2015.
2. SWOG S1415CD: "A Pragmatic Trial to Improve Colony Stimulating Factor Use in Cancer" (32 practices and 2880 patients) was approved by NCI June 10, 2015.

NCI continues to restrict CCDR participation to only those community sites (components) included in the original NCORP grant application. NCI made an exception to the restriction with the addition of six Children Oncology Group (COG) CCDR sites, which were added to allow adequate volume to conduct COG CCDR studies. A significant amount of discord was expressed to the NCI related to the restriction of any additional sites from multiple NCORPs. Currently SCOR has two CCDR sites, Gibbs Cancer Center and Research Institute in Spartanburg, SC and Novant Health Forsyth Medical Center in Winston Salem, NC.

CIRB Transition

All SCOR sites are utilizing the NCI CIRB for available NCI protocols. The next step in the CIRB process is the transition of local IRB-approved protocols to the CIRB. You will need to check the CIRB website (www.ncicirb.org) for the list of currently approved CIRB protocols and compare the list to the protocols you currently have approved through your local IRB. The process of completing the study specific worksheet should not take but a few minutes for each protocol. In your CIRB approved consent template, make sure you have included "Southeast Clinical Oncology Research Consortium Administrative Office" as individuals inspecting/reviewing research records/charts. The transition of all available protocols to the CIRB will benefit you when it comes to research base audits – no review of broadcast SAEs will be done and all approvals/renewals will be done within required time frame.

REMEMBER – Please send your CIRB initial approvals and continuing reviews to the attention of Kim Fulton in the Administrative Office. These approvals/reviews are entered into our database and patient/participant registrations cannot be entered into the database until we have IRB approval verification.

FUTURE ORGANIZATIONAL & RESEARCH BASE MEETINGS

SCOR Spring Conference
April 15, 2016 ..... Presbyterian Hospital, Charlotte, NC

SCOR Fall Conference
October 20, 2016 ..... Grande Dunes Marriott, Myrtle Beach, SC

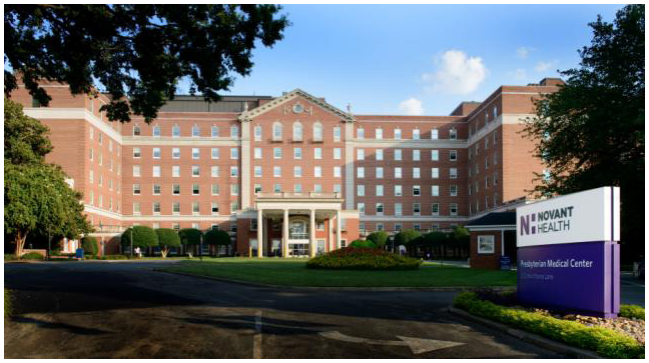
Alliance
May 12-14, 2016 ..... Loews Chicago O'Hare, Rosemont, IL
November 2-5, 2016 ..... Loews Chicago O'Hare, Rosemont, IL
May 11-13, 2017 ..... Chicago, IL
November 1-4, 2017 ..... Loews Chicago O'Hare, Rosemont, IL

NRG (NSABP-RTOG-GOG)
January 21-24, 2016 ..... Atlanta Marriott Marquis, Atlanta, GA
July 14-17, 2016 ..... Sheraton Dallas Downtown, Dallas, TX
January/February 2017 ..... TBA
July 13-16, 2017 ..... Philadelphia Marriott Downtown, Philadelphia, PA

SWOG
April 27-30, 2016 ..... Hyatt Regency San Francisco, San Francisco, CA
September 14-17, 2016 ..... Hyatt Regency Chicago, Chicago, IL
April 26-29, 2017 ..... Hyatt Regency San Francisco, San Francisco, CA
October 11-14, 2017 ..... Hyatt Regency Chicago, Chicago, IL

URCC
September 9-10, 2016 ..... Rochester Airport Marriott, Rochester, NY

WF
October 20-22, 2016 ..... Grande Dunes Marriott, Myrtle Beach, SC



SCOR Spring Meeting
Friday, April 15, 2016
Presbyterian Hospital,
Charlotte, NC